UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,777	04/11/2008	Markus Johnsson	613-110	1595

23117 7590 06/04/2010

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
06/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,777	JOHNSSON ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Prior to noting the restricted groups, it is noted that Claim 1 is a linking claim, as well as lacking unity in-and-of itself, into two distinct linking-claims. The first linking claim (hereinafter referred to as "Claim 1A") composition is noted to be the claim comprising parts (a), (b), and (c); while the second linking claim (hereinafter referred to as "Claim 1B") is noted to be claim 1, comprising only parts (a) and (c) (i.e., part (b) is missing), wherein (a) comprises at least two structure forming amphiphiles.

Group I, claim(s) 2, drawn to a particulate composition comprising at least 50% by weight of at least one structure forming amphiphile, 2-40% by weight of at least one structure swelling amphiphile, and 2-20% by weight of least one dispersion stabilizing polymeric amphiphile, wherein the composition comprises non-lamellar particles or forms such when contacted with an aqueous fluid.

Group II, claim(s) 3, drawn to the composition of Claim 1A, wherein the amphiphilic components comprise at least 50% by weight of amphiphiles having an aqueous soubility of 10E-9 at 25 deg C, relative to the total weight of components a+b+c.

Group III, claim(s) 4, drawn to the composition of Claim 1A, wherein the amphiphilic components comprise at least 70% by weight of amphiphiles having an aqueous soubility of 10E-9 at 25 deg C, relative to the total weight of components a+b+c.

Group IV, claim(s) 5, drawn to the composition of Claim 1A, wherein component (a) comprises at least one lipid chosen from a Markush group of generas.

Group V, claim(s) 6, drawn to the composition of Claim 1A, wherein component (b) comprises at least one swelling agent from a Markush group of generas.

Group VI, claim(s) 7, drawn to the composition of Claim 1A, wherein component (c) comprises at least polymeric agent selected from a Markush group of generas.

Group VII, claim(s) 8, drawn to the composition of Claim 1A, wherein said non-lamellar particles comprise L3 phase and/or reversed hexagonal phase.

Group VIII, claim(s) 9, drawn to the composition of Claim 1A, additionally comprising an active agent.

Group IX, claim(s) 10, drawn to the composition of Claim 1A, wherein component (a) comprises 1-10% by weigth of a cationic lipid, and additionally comprises a nucleic acid active agent.

Group X, claim(s) 11, drawn to the composition of Claim 1A, wherein said non-lamellar particles have a particle size of 1—200 micrometers.

Group XI, claim(s) 12-13, drawn to the composition of Claim 1A, wherein said non-lamellar particles are colloidal.

Group XII, claim(s) 14-15, drawn to the composition of Claim 1A, wherein the composition is non-haemolytic up to a concentration of 0.2% amphiphile.

Group XIII, claim(s) 16, drawn to the composition of Claim 1A, further comprising at least one biologically acceptable carrier or excipient.

Group XIV, claim(s) 17, drawn to the composition of Claim 1A, in a kit.

Group XV, claim(s) 5, drawn to the composition of Claim 1B, wherein component (a) comprises at least one lipid chosen from a Markush group of generas.

Group XVI, claim(s) 7, drawn to the composition of Claim 1B, wherein component (c) comprises at least polymeric agent selected from a Markush group of generas.

Group XVII, claim(s) 8, drawn to the composition of Claim 1B, wherein said non-lamellar particles comprise L3 phase and/or reversed hexagonal phase.

Group XVIII, claim(s) 9, drawn to the composition of Claim 1B, additionally comprising an active agent.

Group XIX, claim(s) 10, drawn to the composition of Claim 1B, wherein component (a) comprises 1-10% by weigth of a cationic lipid, and additionally comprises a nucleic acid active agent.

Group XX, claim(s) 11, drawn to the composition of Claim 1B, wherein said non-lamellar particles have a particle size of 1—200 micrometers.

Group XXI, claim(s) 12-13, drawn to the composition of Claim 1B, wherein said non-lamellar particles are colloidal.

Group XXII, claim(s) 14-15, drawn to the composition of Claim 1B, wherein the composition is non-haemolytic up to a concentration of 0.2% amphiphile.

Group XXIII, claim(s) 16, drawn to the composition of Claim 1B, further comprising at least one biologically acceptable carrier or excipient.

Group XXIV, claim(s) 17, drawn to the composition of Claim 1B, in a kit.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature shared between Claim 1A and 1B is being one of the two compositions. U.S. Patent No. 6,537,575 to Firestone, et al., teaches at least compositions of Claim 1A. To wit, Claim 15 teaches a co-surfactant, which, as seen in the specification, may be LDAO (Section Entitled “Surfactant Detail”); a lipid, which may be DMPC (Section Entitled “Lipid Detail”); and a polymer amphiphile, which may be DMPE-E (Section Entitled "Polymer Detail"). Moreover, when the water is removed from the equation, the various weight percentages of the total are met. Hence, the special technical feature is broken. In addition, U.S. Patent No. 6,593,294 to Baru, et al., teaches compositions of two structure forming lipids which are present at an amount of at least 50%, and a dispersion-stabilizing amphiphile present in an amount of 20% (e.g., Example 1). Hence, the special technical feature is broken. Lastly, each of the separate inventions delineate separate structure and/or functional requirements requiring structural requirements, such that the search and consideration is distinct for each invention, and hence, there exists no general inventive concept between any two inventions.

Claim 1A link(s) inventions I-XIV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), Claim 1A. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the

limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 1b link(s) inventions XV-XXIV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), Claim 1A. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Applicant should elect Inventions IV or XV:

Applicant should elect a single genera of lipid components, from the three listed in claim 5, as well as a single species of such genera, as supported by the specification.

If Applicant should elect Invention V:

Applicant should elect a single genera of swelling agent from the 5 listed in Claim 6, as well as a single species of such genera, as supported by the specification.

If Applicant should elect Invention VI or XVII:

Applicant should elect a single polymeric agent from the 4 generas listed in Claim 7, as well as a single species of such genera, as supported by the specification.

If Applicant should elect Invention VII or XVIII:

Applicant should elect either L3 phase or reversed hexagonal phase, as listed in Claim 8.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: All claims are generic as no species is listed, only generas.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633